

## **Arsenal Medical Launches EMBO-02 Study for NeoCast™ to Assess Treatment of Chronic Subdural Hematoma**

*First Patient Enrolled in Trial to Evaluate Safety and Feasibility of Innovative Embolic Agent in Expanded Patient Population Utilizing Middle Meningeal Artery Embolization (MMAe)*

**WALTHAM, MA - November 14, 2024** — Arsenal Medical, a clinical-stage company developing medical devices from innovative biomaterials, today announced the initiation of the EMBO-02 clinical study of NeoCast™ to treat chronic subdural hematomas (cSDH). NeoCast is a first-of-its-kind, shear-responsive, non-adhesive, solvent-free, liquid embolic material designed for deep distal penetration. The study is enrolling up to 10 subjects at three sites in Australia; the first patient has been enrolled at Monash Health, Victoria, Australia.

“We are encouraged by our experience with NeoCast in cSDH. The initial case was an excellent translation of middle meningeal embolization from EMBO-01, which studied hypervascular brain tumors. NeoCast performed predictably throughout injection and provided robust distal occlusion, further demonstrating its unique properties, which sets it apart from current embolic products,” said Lee-Anne Slater, MBBS MMed FRANZCR, Interventional Neuroradiologist at Monash Health and the principal investigator of both EMBO-02 and EMBO-01 trials. “Better performing, innovative solutions are needed to manage this significant neurovascular condition. We look forward to continuing enrollment in EMBO-02 and uncovering the potential for NeoCast for this population.”

Upma Sharma, Ph.D., President and CEO of Arsenal Medical commented, “Recent data suggest middle meningeal artery embolization (MMAe) procedures for treating cSDH are estimated to rapidly increase in frequency and are expected to surpass those for large vessel stroke.<sup>1</sup> The launch of EMBO-02, our second study with NeoCast, is an important milestone for the company and a next step toward delivering a differentiated embolic solution. I am grateful to all of our clinical and scientific collaborators who are helping us to advance our next-generation embolic material and, most importantly, the patients who participate in these important studies.”

### **About Chronic Subdural Hematoma (cSDH)**

cSDH is the persistent bleeding of an injured vessel in the membrane that protects the brain (dura). It is typically caused by a fall or injury to the head (including minor head trauma) and can result in significant physical and cognitive decline. It is the most common neurosurgical condition in those 65 and older and has been categorized as a sentinel health event in the elderly. MMAe is an emerging minimally invasive procedure to treat and prevent the recurrence of cSDH.

### **About EMBO-02**

EMBO-02 is an open-label, multi-center, prospective clinical trial to evaluate the early safety and feasibility of Arsenal Medical’s NeoCast to embolize target vessels of the subject’s middle meningeal artery (MMA) in order to treat cSDH and potentially reduce hematoma recurrence. EMBO-02 is the second study for NeoCast, following EMBO-01 which demonstrated safety and feasibility in hypervascular brain tumors.

### **Primary endpoints for EMBO-02 include the following:**

- Safety, defined as freedom from device-related disabling stroke or neurological death within 30 days of the embolization procedure.
- Feasibility, defined as the successful injection of NeoCast into the MMA, resulting in complete occlusion at or distal to the point of embolysate injection.

### **About NeoCast™**

NeoCast™ is a next-generation, solvent-free, non-adhesive liquid embolic material designed to preferentially reach distal microvasculature. Doing so provides a complete cast of the vessel, achieving robust occlusion to stop unwanted blood flow. Developed with funding from the National Cancer Institute, NeoCast leverages shear-thinning science to reach the smallest vessels and halt blood flow to tumors and injured or diseased tissues. Its unique material characteristics deliver enhanced control during injection, eliminating harsh solvents and adhesive glues often found in current liquid embolic products. NeoCast addresses the limitations of existing embolic products for deep penetration into the microvasculature, offering easy deployment and consistent performance.

### **About Arsenal Medical**

Arsenal Medical is a clinical-stage company that creates innovative biomaterials to solve challenging and underserved medical problems. Its lead products target neurovascular and trauma conditions. The company was founded by academic luminaries Robert Langer and George Whitesides, along with serial entrepreneur-investor Carmichael Roberts, who shared a vision for how materials can transform medical devices. [www.arsenalmedical.com](http://www.arsenalmedical.com)

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### **References:**

1. Rai AT, Halak AA, Lakhani DA, *et al* Population-based estimates suggest middle meningeal artery embolization for subdural hematomas could significantly expand the scope of neurovascular therapies *Journal of NeuroInterventional Surgery* Published Online First: 11 April 2024. doi: 10.1136/jnis-2024-021686